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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,167	12/29/2006	Akito Tanaka	43512-104209	6601

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EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
08/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent-ch@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/573,167	TANAKA ET AL.	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-18* is/are pending in the application.

4a) Of the above claim(s) *10,11,15 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14,16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *10-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 12-14, 16, and 18, with traverse, filed March 28, 2008 is acknowledged and has been entered. Claims 10, 11, 15 and 17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 10-18 are pending. Claims 12-14, 16, and 18 are under examination.

2. Applicant traverses the restriction requirement on the grounds that the present invention is characterized by mixing a protein sample with an affinity resin at least two times for an assay of the specificity of the protein bound on the affinity resin. Applicant contends that Group I and Group II should be examined together since they share the same corresponding technical feature.

Applicant's argument is not persuasive because the claims recited in Groups I and II do not recite the common corresponding technical feature (supra) which Applicant deems to render the two groups of claims combinable. Additionally, literature search for each method is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

4. To obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d), a certified English translation of the foreign application must be submitted. 37 CFR 41.154(b) and 41.202(e). Failure to provide a certified translation may result in no benefit being accorded for the non-English application. Accordingly, the priority date of this instant application is October 15, 2004, which is the filing date of the International Application which has an English translation that was filed March 21, 2006.

Specification

5. The specification is narrative in form and replete with non-idiomatic English. A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 12-14, 16, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite in being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. In this case, the essential structural and functional cooperative relationships between the solid phase carrier and inert substance in (i) and the solid phase carrier and ligand in (ii), and the molecule in the sample are not clearly defined so as to establish what product is intended to be resulted in (iii) for extraction. As recited, it is unclear how the inert substance in (i) relates to the molecule in (iii), i.e. does the inert substance have binding affinity to the molecule as the ligand? Do the inert substance and ligand bind different epitopes present in the molecule so as to form a sandwich format? What specific complexes are expected to be formed? Should a separation step to separate bound from unbound components be performed? Is there more than one molecule for binding of the ligand? Please clarify.

Claim 12, step (iii) is confusing because it is unclear how a molecule bound to ligand immobilized to solid phase is extracted, i.e. from the ligand-immobilized to solid phase, to thus obtain "ligand-immobilized solid phase extract 1." It is specifically unclear why the "extract 1" which contains the "extracted molecule" still comprises "ligand-immobilized solid phase." Please clarify. Is a separation between bound or unbound components intended instead? Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant

intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). In this case, the term "extracting" in claim 12 appears to be used by the claim to mean "separation between bound and unbound components", while the accepted meaning is "separation of a component from another component which it is bound to." The term is indefinite because the specification does not clearly redefine the term. Same analogous comments and problems apply to steps (vii) and (viii).

Claim 12 is further indefinite in being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. In this case, the essential structural and functional cooperative relationships between the solid phase carrier and ligand in (iv) and the solid phase carrier and ligand in (v), and the molecule in the sample are not clearly defined so as to establish what product is intended to be resulted in (vi) for extraction. As recited, it is unclear how the ligand in (iv) relates to the molecule in (vi), i.e. are the ligands in iv) and v) same or different and do the ligands in iv) and v) bind to a same or different epitope of the molecule so as to form a sandwich format. What specific complexes are expected to be formed? Should a separation step to separate bound from unbound components be performed? Is there more than one molecule for binding of the ligand? Please clarify.

Claim 12, step (vi) is confusing because it is unclear how a molecule bound to ligand immobilized to solid phase is extracted, i.e. from the ligand-immobilized to solid phase, to thus obtain "ligand-immobilized solid phase extract 2." It is specifically

unclear why the "extract 2" which contains the "extracted molecule" still comprises "ligand-immobilized solid phase." Please clarify. Is a separation between bound or unbound components intended instead? Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). In this case, the term "extracting" in claim 12 appears to be used by the claim to mean "separation between bound and unbound components", while the accepted meaning is "separation of a component from another component which it is bound to." The term is indefinite because the specification does not clearly redefine the term. Same analogous comments and problems apply to steps (vii) and (viii).

Accordingly, the recitations of "the molecule [contained in]" and "the ligand" in each one of (iii) to (viii) all lack clear antecedent basis.

Claim 12 is also confusing because it is unclear how the comparing and analyzing step in (vii) and identifying step in (viii) are performed since the nature of the resulted products is not clearly defined. Additionally, it is unclear how the comparing step and identifying step are effected in the absence of a baseline value for each of the inert substance and the ligand in the first portion of the sample and the ligand in each one of iv) and v) of the second portion of the sample.

Claim 14 is vague and indefinite in reciting, "structurally similar" because the term "structural" and "similar" are subjective terms that lack a comparative basis for defining their metes and bounds. Additionally, it is unclear as to whether or how "structural similarity" between the inert substance and the ligand should dictate their binding specificity towards a molecule. Please clarify.

Claim 14 lacks antecedent basis for the recitation of "the subject ligand."

Claim 18 is confusing in lacking clear antecedent basis for the recitation of "the molecule binding to the ligand" because there are several occurrences of molecule binding to a ligand in claim 12, i.e. (iii), (iv), (v), and (vi).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 12, 14, 16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindmo (US Patent 5,585,241).

Lindmo discloses a flow cytometric method of determining specific binding of a molecule (analyte) to a ligand. In practice, a sample portion (first sample portion) containing the desired molecule is treated with a predetermined amount of solid phase carriers (monodisperse particles) having immobilized thereto a ligand (specific binding partner) having affinity for the molecule; thus, forming a first treated sample. The first

treated sample is further treated with a different set of predetermined amount of solid phase carriers having immobilized thereto a ligand analogue having affinity for the molecule; thus, forming a first twice-treated sample. The two different sets of ligand carrying solid phase carriers are distinguishable from each other by flow cytometry (Abstract and c. 5, lines 20-44). Each one ligand carrying solid phase particle carries a ligand or a ligand analog. The ligand and the ligand analogue have the same binding specificity but different binding affinity for the molecule and are independently and simultaneously detected. The label for the method may be fluorescent or microparticulate such as colloidal gold particles (c. 4, lines 56-67). Another portion of the sample may also be treated with another distinguishable solid phase carrier having immobilized thereto an inert substance (irrelevant antibody) so as to form a second treated sample to address non-specific binding (c. 5, lines 59-67). According to Lindmo, treatment and determinations of molecule binding to more different sets of predetermined particles carrying ligands that bind the molecule, i.e. a second twice treated sample, increases reliability of assays and reveals deviation from normal performance of the assays, i.e. calibration (c. 6, lines 5-18). The molecules bound to the ligand may be separated (extracted) from unbound components so as to reduce non-specific binding, but is not required (c. 5, lines 52-58). The molecules contained in the sample or samples (i.e. extract 1 and extract 2) are detected, quantified and are compared and analyzed so as to determine extent of binding specificity of the molecule for the ligand. The binding (association) constant of the molecule binding to the ligands is measured and calculated (c. 5, lines 67-51).

Since claims 12-14, 16 and 18 are so unclear as to the nature of the method and characterization and interrelationship of the structural components involved in the method and since the teachings of Lindmo reads on the claimed invention, it is deemed that claims 12-14, 16, and 18 are anticipated by Lindmo. Additionally, it is proper for purposes of this anticipation rejection to interpret the claims as plainly as they are recited because unpatented claims are given the broadest reasonable interpretation consistent with the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindmo (US Patent Number 5,585,241) in view of Higgs et al. (US Patent 5,88,177).

Lindmo is discussed supra. Lindmo differs from the instant invention in failing to teach that the inert substance is stearic acid.

Higgs et al. disclose that stearic acid or stearate is a known inert substance that is hydrophobic in nature; hence, capable of producing non-specific protein adsorption in particulate materials (Abstract and c. 10, lines 63-67).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute stearic acid as taught by Higgs for use as non-specific inert substance in the method of Lindmo because stearic acid constitutes an obvious variation of inert substances known in the art capable of producing non-specific protein adsorption.

9. No claims are allowed.

Remarks

10. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Karlsson (US Patent 5,753,518) disclose a method of determining as to whether binding (affinity and kinetic properties) of a molecule (common receptor) to a ligand (low molecular weight ligand) is specific comprising immobilizing the molecule into a solid surface (sensing surface) and then mixing therein known proportions of ligand and

ligand analogue (inert substance), the response of which on the sensing surface is substantially higher than that of the low molecular weight ligands. Thereafter, the ligand mixture is contacted with the sensing surface, and the response is measured and compared with the response of each mixture with that of the ligand analogue alone, the difference of the ligand analogue response is representative of affinity and kinetic properties of the ligand. (Abstract)

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday to Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should ,you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

July 26, 2008